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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,937	10/13/2004	Hubert Thoma	H-32407A	6977

1095 7590 11/20/2006

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER

LEVY, NEIL S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/506,937	THOMA ET AL.	
	Examiner	Art Unit	
	NEIL LEVY	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,22,24-30 and 32-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,22,24-30 and 32-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/15/06</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections of record are withdrawn in view of applicant's arguments and amendments of 5/25/06.

Claim Rejections - 35 USC § 103

Claim 21-22, 24-30, 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over PATEL et al W00137808 in view of JONES '57 or FRIEDMAN -3824233 or MALNOE et al W002/071874 or ALFORD 3937825.

PATEL utilizes sugar and lactose carrier [substrates-page 51, 4] with non-limited actives, including benazepril [page 7, 14]. The actives are coated on sugar beads [example 1] of the instant size. Example 6 provides an additional protective seal coating, of PVP [the instant masking coating]. Surfactants and other ingredients may be present, as the instant language is in open guise. Additives can include minerals, proteins, aromatics as essential oils or alcohols [page 58]. PATEL provides actives coated on sugar and again coated, as granules, pellets, microcapsules, tablets or capsules [page 51, line 4]. Preparatory additives and processes are also mentioned, as commonly utilized to prepare the pharmaceutical compositions [page 52, 53, 5].

PATEL did not discuss possible dosage forms or modes of delivery. JONES does- in feed, for example with antibiotics [page 832, 833] poultry [page 834, 2nd paragraph] for swine, or DES in lambs or cattle [page 834].

So does FRIEDMAN [column 11, top] for anthelmintics, MALNOE [page 4] for pet food vitamins, with yeast [page 9, top] as a part of the pet food, and HOFFMAN as coccidiostats [column 4; column 6, bottom] and ALFORD [column 2, lines 18-22] for anthelmintics provided with conventional tableting ingredients-lactose, sucrose [column 2, bottom-column 3, line 20] and coated.

Patel & Jones or Friedman show the instant masked drug in pellet or tablet but not specifically with animal feed. However, the secondary references show it is common to mix drugs in feed to treat animals.

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It would have been obvious to a person of ordinary skill in the art at the time the invention was made, desiring to utilize masked compositions, to use one of those well known in the art, as exemplified by the primary references, with selection of the active as required at concentration effective to control the pest or disease of concern.

All the critical elements of the instant invention are disclosed. The amounts and proportions of each ingredient are result effective parameters chosen to obtain the desired effects. It would be obvious to vary the form of each ingredient to optimize the effect desired, depending upon the particular pest species, growth desired, or disease of interest.

Applicant has not provided any objective evidence of non-obvious or unexpected results that the administration of the particular ingredients' or concentrations or mixing with feed provides any greater or different level of prior art expectation as claimed, and the use of ingredient for the functionality for which they are known to be used is not a basis for patentability.

Applicant's arguments filed 5/25/06 have been fully considered but they are not persuasive. Applicant's arguments have been considered in the new rejections to the extent Patel applies.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619.

The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


NEIL LEVY
Primary Examiner
Art Unit 1615
